

# Exhibit 9

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY  
CAMDEN VICINAGE**

IN RE: VALSARTAN, LOSARTAN, AND  
IRBESARTAN PRODUCTS LIABILITY  
LITIGATION

Hon. Robert. B. Kugler

This Document Relates To:

Civ. No. 19-2875 (RBK/JS)

*All Actions*

**PLAINTIFFS' THIRD AMENDED NOTICE OF VIDEOTAPED DEPOSITION  
TO AUROBINDO PHARMA LIMITED, AUROBINDO USA, INC., AND  
AUROLIFE, LLC PURSUANT TO FED. R. CIV. P. 30(b)(6)**

TO: Jessica M. Heinz, Esq.  
Cipriani & Werner  
450 Sentry Parkway, Suite 200  
Blue Bell, PA 19422

*Counsel for Defendants Aurobindo Pharma Limited, Aurobindo USA, Inc. and Aurolife  
Pharma, LLC*

PLEASE TAKE NOTICE that, pursuant to Fed. R. Civ. P. 30(b)(6), Plaintiffs will take the deposition upon oral examination of one or more designated corporate representatives with regard to the topics set forth on Exhibit A attached hereto. The deposition(s) will commence on a date to be determined, at 9:00 a.m., at a location to be determined, and continue from day to day as needed.

The deposition(s) will be taken upon oral examination before an officer authorized to administer oaths and will continue from day to day, until completed. Testimony given during the deposition will be recorded by sound video recording and stenographic means.

DATED this \_\_\_\_ day of November, 2020.

**MAZIE SLATER KATZ & FREEMAN, LLC**

By: /s/ Adam M. Slater

Adam M. Slater  
103 Eisenhower Parkway, Suite 207  
Roseland, New Jersey 07068  
Telephone: 973-228-9898

*Attorneys for Plaintiffs*

**CERTIFICATE OF SERVICE**

I, Adam M. Slater, hereby certify that on November, 2020, I caused true and correct copies of the foregoing to be transmitted via ECF to all counsel having registered an appearance on ECF, with courtesy copies served on counsel for Aurobindo Pharma Limited, Aurobindo USA, Inc. and Aurolife Pharma, LLC, and Defendants' liaison counsel, via email.

DATED this \_\_\_\_ day of November, 2020.

**MAZIE SLATER KATZ & FREEMAN, LLC**

By: /s/ Adam M. Slater  
Adam M. Slater  
103 Eisenhower Parkway, Suite 207  
Roseland, New Jersey 07068  
Telephone: 973-228-9898

***Attorneys for Plaintiffs***

## **EXHIBIT A**

All topics reference information and documents known to, and/or in the possession, custody, or control, of Aurobindo, in the ordinary course of its business.

All references to Aurobindo refer to all entities involved in the manufacture of valsartan API and/or finished dose sold by Aurobindo Pharma Limited, Aurobindo Pharma USA, Inc. and/or Aurolife Pharma, LLC in the United States.

All references to the “API,” or Aurobindo’s API are defined to include the valsartan API manufactured, sold, or distributed by Aurobindo, including valsartan API used in drugs marketed and sold in the United States

All references to “finished dose” or Aurobindo’s finished dose are defined to include all valsartan finished dose manufactured by Aurobindo, including valsartan finished dose sold in the United States.

In accordance with the Court’s Macro Discovery Order (ECF Doc No. 303), the terms “communications with any regulatory authority,” “disclosures to regulatory authorities,” and “filings with regulatory authorities” are limited to communications with the United States Food and Drug Administration, except insofar as the communications relate to regulatory inspection reports, warning letters, 483-like documents, responses to those documents, root cause analyses, and actual or potential nitrosamine contamination prior to July 2018, that were sent to or received from any foreign regulatory body during the designated relevant time period.

All references to testing are defined to include testing capable of identifying the presence of nitrosamine contamination (i.e. NDMA, NDEA, NMBA), and/or detecting other carcinogens, general toxic impurities (including genotoxic impurities), and residual solvents, in connection with the manufacture and contents of Aurobindo API or finished dose, and include but are not limited to the following:

- Gas Chromatography (GC)
- Gas Chromatography- Flame Ionization Detector (GC-FID)
- Gas Chromatography- Mass Spectrometry (GC-MS)
- Gas Chromatography- tandem Mass Spectrometry (GC-MS/MS)
- Gas Chromatography- Selective Ion Monitoring Mass Spectrometry (GC-SIM MS)
- Gas Chromatography- High Resolution Mass Spectrometry (GC-HRMS)
- Gas Chromatography- Atomic Emission Spectrometry (GC-AES)
- Gas Chromatography- Flame Photometric Detector (GC-FPD)
- Gas Chromatography- Nitrogen Phosphorus Detector (GC-NPD)
- Gas Chromatography- Thermal Conductivity Detector (GC-TCD)
- Gas Chromatography- Photoionization Detector (GC-PID)
- Gas Chromatography- Electrolytic Conductivity Detector (GC-ELCD)
- Headspace Gas Chromatography (HS-GS)
- Liquid Chromatography (LC)
- High Performance Liquid Chromatography (HPLC)

- Liquid Chromatography-Mass Spectrometry (LC-MS)
- Liquid Chromatography-tandem Mass Spectrometry (LC-MS/MS)
- Liquid Chromatography- Selective Ion Monitoring Mass Spectrometry (LC-SIM MS)
- Liquid Chromatography- High Resolution Mass Spectrometry (LC-HRMS)
- Atomic Absorption Spectroscopy (AAS)
- Atomic Emission Spectrometry (AES)

### **Nitrosamine Contamination**

1. The cause of the contamination of Aurobindo's valsartan API with nitrosamines, including, but not limited to, NDMA and NDEA.
2. The root cause investigation for the nitrosamine impurities, including NDMA and NDEA in the Aurobindo API.
3. Any assessment or root cause analysis conducted by Lantech Pharmaceuticals with regards to NDMA and NDEA contamination in recycled or recovered solvents.

### **Testing**

4. The testing performed by Aurobindo or its agents, to evaluate the purity and contents of Aurobindo's API.
5. The testing performed by any entity or person other than Aurobindo or its agents but known to Aurobindo, to evaluate the purity and contents of Aurobindo's valsartan API.
6. The testing performed by Aurobindo or its agents, to evaluate the purity and contents of Aurobindo's finished dose.
7. The testing performed by Aurobindo or its agents to evaluate the purity and contents of recovered or recycled solvents provided by Lantech Pharmaceuticals.
8. The testing performed by any entity or person other than Aurobindo or its agents but known to Aurobindo, to evaluate the purity and contents of Aurobindo's finished dose.
9. The chromatogram and mass spectrometry results for all testing by Aurobindo or its agents of Aurobindo's valsartan API.
10. The chromatogram and mass spectrometry results for all testing by any entity or person other than Aurobindo or its agents but known to Aurobindo, of Aurobindo's valsartan API.
11. The chromatogram and mass spectrometry or other results for all testing by Aurobindo or its agents of Aurobindo's finished dose.
12. The chromatogram and mass spectrometry or other results for all testing by any entity or person other than Aurobindo or its agents but known to Aurobindo, of Aurobindo's finished dose.

13. Aurobindo's evaluation of the potential risks to the purity or contents of Aurobindo's API posed or caused by solvents used during the manufacturing process.
14. The chromatogram and mass spectrometry results for all testing by Aurobindo or its agents of the solvents utilized in the manufacture of Aurobindo's valsartan API.
15. The chromatogram and mass spectrometry results for all testing by any entity or person other than Aurobindo or its agents but known to Aurobindo, of the solvents utilized in the manufacture of Aurobindo's API.
16. The extent of the actual and potential nitrosamine contamination of Aurobindo's valsartan API and valsartan finished dose sold in the United States, both in terms of the concentration per pill, and across all of the lots/batches.

**Quality Assurance and Quality Control Activities**

17. Aurobindo's Standard Operating Procedures ("SOPs"), policies or procedures intended to prevent, detect, or act in response to any impurity or contamination, for example carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, in connection with the manufacture and contents of Aurobindo's valsartan API. (The parties to meet and confer to identify the relevant SOP's, policies, or procedures.)
- 17.18. Aurobindo's Standard Operating Procedures ("SOPs"), policies or procedures intended to prevent, detect, or act in response to any impurity or contamination, for example carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, in connection with the manufacture and contents of Aurobindo's valsartan finished dose. (The parties to meet and confer to identify the relevant SOP's, policies, or procedures.)
19. Aurobindo's application of cGMPs intended to prevent, detect, or act in response to any impurity or contamination, for example carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, in connection with the manufacture of Aurobindo's valsartan API. (The parties to meet and confer to identify the relevant cGMP's.)
- 18.20. Aurobindo's application of cGMPs intended to prevent, detect, or act in response to any impurity or contamination, for example carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, in connection with the manufacture of Aurobindo's valsartan finished dose. (The parties to meet and confer to identify the relevant cGMP's.)
- 19.21. Aurobindo's SOPs/policies/procedures intended to prevent, detect, or act in response to any impurity or contamination, for example carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, in connection with procurement of recovered or recycled solvents, and selection of vendors to provide such services. (The parties to meet and confer to identify the relevant SOP's, policies, or procedures.)

**Process Development**

- 20.22. The development of each Drug Master File, including any risk assessments conducted on starting materials, or solvents, for Aurobindo's valsartan API.
- 21.23. The use of solvents, and the Tetrazole ring formation step, in the manufacturing process for Aurobindo's valsartan API, including: (1) the reasons for each, and any modifications, (2) the testing and evaluation in connection with each, including any modification, and (3) the relationship between each, including any modifications, and the nitrosamine contamination of Aurobindo's valsartan API.
- 22.24. Any evaluation conducted by or on behalf of Aurobindo with regard to health or safety issues arising from the use of solvents, and the Tetrazole ring formation step, and in



particular potential nitrosamine impurities, in the manufacturing process for Aurobindo's valsartan API.

23:25. Aurobindo's evaluation and knowledge of the risk of the creation of nitrosamines including NDMA and NDEA as a result of the manufacturing process for Aurobindo's valsartan API.

24:26. Aurobindo's evaluation and knowledge of the risks of using recovered or recycled solvents in the manufacture of Aurobindo's API and finished dose.

27. Aurobindo's evaluation and knowledge of the health risks of exposure to nitrosamines including NDMA and NDEA, including but not limited to as a contaminant of Aurobindo's valsartan API.

28. Aurobindo's evaluation and knowledge of the health risks of exposure to nitrosamines including NDMA and NDEA, including but not limited to as a contaminant of Aurobindo's valsartan finished dose.

#### **Communications with Regulatory Agencies**

25:29. The communications with any regulatory authority, including but not limited to the FDA, with regard to the use of solvents, and the Tetrazole ring formation step, in the manufacturing process for Aurobindo's valsartan API.

30. Aurobindo's communications with regulatory authorities, including the FDA, with regard to the actual or potential contamination of Aurobindo's valsartan API with nitrosamines including NDMA and NDEA.

26:31. Aurobindo's communications with regulatory authorities, including the FDA, with regard to the actual or potential contamination of Aurobindo's valsartan finished dose with nitrosamines including NDMA and NDEA.

27:32. Aurobindo's filings with regulatory authorities, including the FDA, regarding manufacturing process changes for Aurobindo's Valsartan API Drug Master Filings.

#### **Aurobindo's Communications with Finished Dose Customers and Downstream Customers**

33. Aurobindo's oral and written communications with its valsartan API Customers (including vertically integrated facilities) or other downstream entities (i.e. wholesalers, retailers, consumers, TPP's) regarding quality, purity, or contamination issues related to the Aurobindo API.

28:34. Aurobindo's oral and written communications with its valsartan finished dose Customers (including vertically integrated facilities) or other downstream entities (i.e. wholesalers, retailers, consumers, TPP's) regarding quality, purity, or contamination issues related to the Aurobindo finished dose.

35. Aurobindo's oral and written statements to finished dose manufacturers, wholesalers, retailers, and consumers with regard to the contents and purity of Aurobindo's valsartan API.
- ~~29.~~36. Aurobindo's oral and written statements to finished dose manufacturers, wholesalers, retailers, and consumers with regard to the contents and purity of Aurobindo's valsartan finished dose.
37. Aurobindo's product recall for valsartan API, including who Aurobindo communicated with, how, about what, and the retention of recalled or sequestered Aurobindo valsartan API, including as a component of finished dose.
- ~~30.~~38. Aurobindo's product recall for valsartan finished dose, including who Aurobindo communicated with, how, about what, and the retention of recalled or sequestered Aurobindo valsartan finished dose.
- ~~31.~~39. All credits, indemnification, refunds, and/or penalties paid or provided by or to Aurobindo (i.e. to/from customers, regulatory agencies) in connection with the nitrosamine contamination of Aurobindo's valsartan API and finished dose.

### **Compliance with cGMPs**

- ~~32.~~40. Aurobindo's compliance or non-compliance with cGMPs intended to prevent, detect, or act in response to any impurity or contamination, for example carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, as it relates to the manufacture, quality assurance, quality control, and sale of Aurobindo's API and finished dose. (The parties to meet and confer to identify the relevant cGMP's.)
- ~~33.~~41. The policies, practices, procedures and trainings for monitoring compliance with cGMPs intended to prevent, detect, or act in response to any impurity or contamination, for example carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, in the manufacture of Aurobindo's valsartan API and valsartan finished dose. (The parties to meet and confer to identify the relevant cGMP's.)
- ~~34.~~42. The policies, practices, procedures and trainings intended to prevent, detect, or act in response to any impurity or contamination, for example carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, for monitoring material providers (such as Lantech Pharmaceuticals) and their compliance with cGMPs intended to prevent, detect, or act in response to any impurity or contamination, for example carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents,. (The parties to meet and confer to identify the relevant cGMP's.)

### **Product Tracing**

43. Tracing of batches and lots of Aurobindo's valsartan API sold downstream and ultimately intended for use by consumers in the United States. (the parties to meet and confer to identify relevant documents).

- 35.44. Tracing of batches and lots of Aurobindo's valsartan finished dose sold downstream and ultimately intended for use by consumers in the United States. (the parties to meet and confer to identify relevant documents).
- 36.45. The pricing of Aurobindo's valsartan API that was ultimately sold in the United States (the parties to meet and confer to identify relevant documents).
- 37.46. The pricing of Aurobindo's valsartan finished dose that was ultimately sold in the United States (the parties to meet and confer to identify relevant documents).
- 38.47. The gross and net profits to Aurobindo from the sale of Aurobindo's valsartan API in the United States (the parties to meet and confer to identify relevant documents).
- 39.48. The gross and net profits to Aurobindo from the sale of Aurobindo's valsartan finished dose in the United States (the parties to meet and confer to identify relevant documents).
- 40.49. The quantity/units of Aurobindo's valsartan finished dose sold in the United States (the parties to meet and confer to identify relevant documents).
- 41.50. Aurobindo's valsartan API sales and pricing data produced by you in this litigation (sample documents to be provided ahead of deposition during meet and confer process).
- 42.51. Aurobindo's valsartan finished dose sales and pricing data produced by you in this litigation (sample documents to be provided ahead of deposition during meet and confer process).